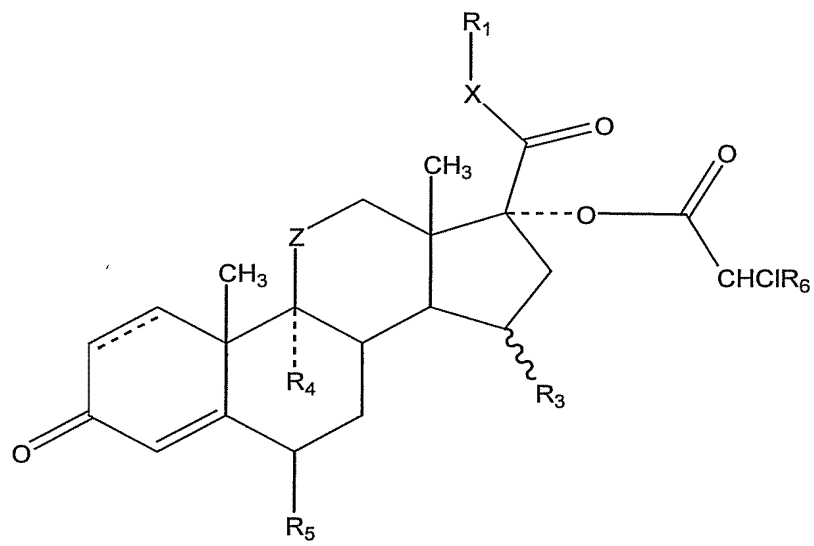


CLAIM AMENDMENTS

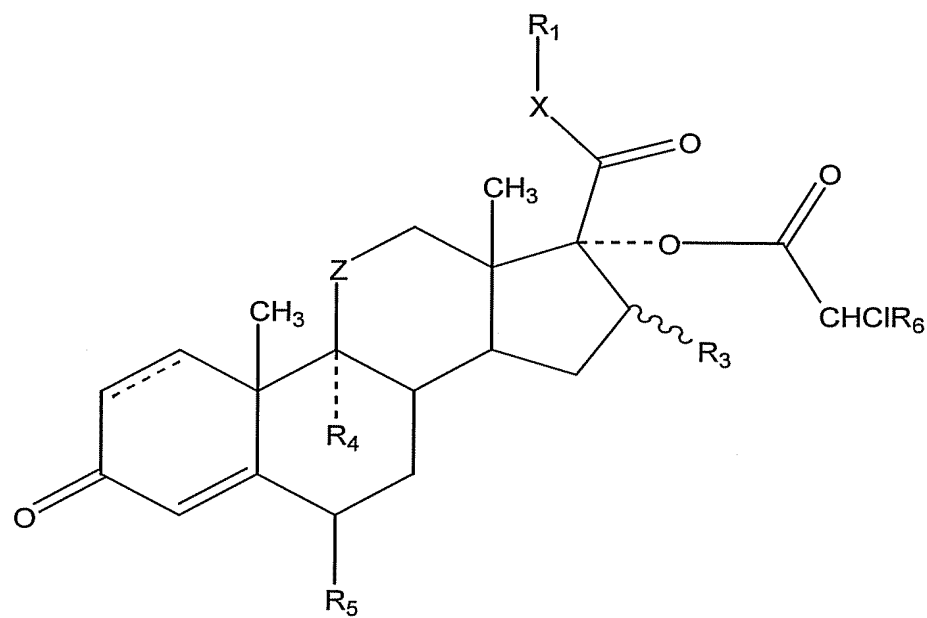
Please amend the claims as shown in the claim listing:

1. (currently amended) A composition comprising particles of at least one soft steroid and at least one excipient, wherein said soft steroid is defined by the structural formula I:



I

or the structural formula II:



II

wherein

R₁ is C₁-C₄ alkyl, which is unsubstituted or which bears one substituent selected from the group consisting of chloro, fluoro, C₁-C₄ alkoxy, C₁-C₄ alkythio, C₁-C₄ alkylsulfinyl and C₁-C₄ alkylsulfonyl;

R₃ is hydrogen, α -hydroxy, β -hydroxy, α -methyl, β -methyl, =CH₂, or α - or β -OC(O)CHCl₂;

R₄ is hydrogen, fluoro, or chloro;

R₅ is hydrogen, fluoro, chloro or methyl;

R₆ is hydrogen, chloro or methyl for formula I, or R₆ is hydrogen or methyl for formula II;

X is -O- or -S-;

Z is carbonyl, β -hydroxymethylene or β -chloromethylene;

the dotted line in ring A indicates that the 1,2-linkage is saturated or unsaturated;

wherein said at least one soft steroid particles have a volume mean diameter of less than about 20 micrometers and said at least one excipient particles have a volume mean diameter in the range of about 10 to about 1000 micrometers, wherein the volume mean diameter of the soft steroid particles is more than 3 times smaller than the mean diameter of the excipient particles.

2-3. (canceled)

4. (currently amended) A composition as claimed in claim 1 or 4 [[3]], wherein the volume mean diameter of the soft steroid particles is more than 5 times smaller than the mean diameter of the excipient particles.

5. (currently amended) A composition as claimed in any one of the preceding claims, wherein at least 50 wt % of the soft steroid particles have a diameter less than about 10 μ m.

6. (original) A composition as claimed in claim 5, wherein at least 50 wt % of the soft steroid particles have a diameter less than about 5 μ m.

7. (original) A composition as claimed in claim 6, wherein at least 50 wt % of the soft steroid particles have a diameter less than about 3 μ m.

8. (canceled)

9. (currently amended) A composition as claimed in claim 1 ~~any one of the preceding claims~~,

wherein the volume mean diameter of the said soft steroid particles is less than about 10 μm .

10. (currently amended) A composition as claimed in claim 9 [[8]], wherein said soft steroid particles have an average volume mean diameter of about 5 μm or less.

11. (currently amended) A composition as claimed in claim 10 [[9]], wherein said soft steroid particles have an average volume mean diameter from about 0.5 μm to about 5 μm .

12. (currently amended) A composition as claimed in claim 11 [[10]], wherein said soft steroid particles have an average volume mean diameter from about 1.5 μm to about 3 μm .

13. (currently amended) A composition as claimed in claim 1 or 4 ~~any one of the preceding claims~~, wherein said excipient particles have an average volume mean diameter in the range from about 15 μm to about 250 μm ~~micrometers~~.

14. (currently amended) A composition as claimed in claim 13 [[12]], wherein said excipient particles have an average volume mean diameter in the range of about 20 μm to about 100 μm ~~micrometers~~.

15. (currently amended) A composition as claimed in claim 1 or 4 ~~any one of the preceding claims~~, wherein at least about 30 wt % of the excipient particles have a diameter less than 100 μm .

16. (original) A composition as claimed in claim 15, wherein no more than about 50 wt % of the excipient particles have a diameter less than about 10 μm .

17. (currently amended) A composition as claimed in claim 1 or 4 ~~any one of the preceding claims~~, wherein at least about 50 wt % of the excipient particles have a diameter less than 500 μm .

18. (currently amended) A composition as claimed in claim 1 or 4 ~~any one of the preceding claims~~, wherein said composition is a dry homogenous blend.

19. (currently amended) A composition as claimed in claim 1 or 4 ~~any one of the preceding~~

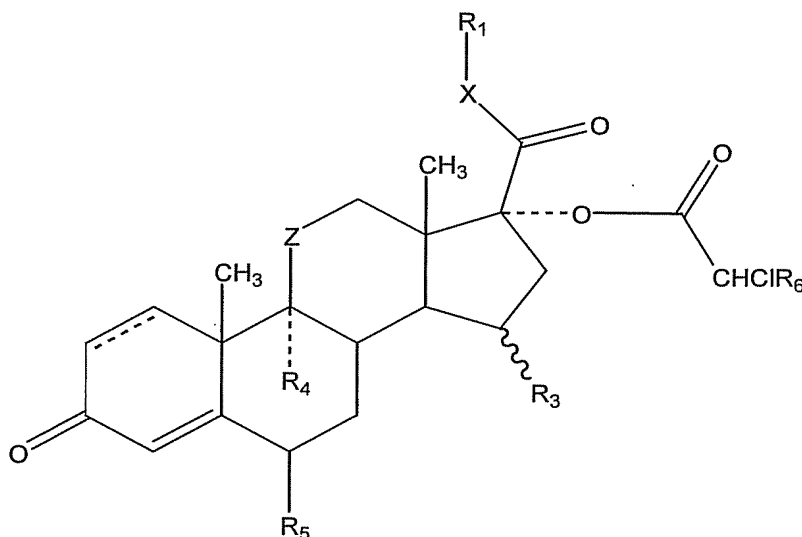
claims, wherein said composition is formed by mixing of the soft steroid and excipient particles.

20. (currently amended) A composition as claimed in claim 1 or 4 ~~any one of the preceding claims~~, wherein the concentration of said soft steroid particles is up to about 50% by wt in relation to the excipient particles.

21. (currently amended) A composition as claimed in claim 20, wherein the concentration of said soft steroid particles is in the range of about 1 percent to about 10 percent by wt in relation to the excipient particles.

22. (currently amended) A composition as claimed in claim 21, wherein the concentration of said soft steroid particles is in the range of about 3 percent to about 7 percent by wt in relation to the excipient particles.

23. (currently amended) A composition as claimed in claim 1 or 4 ~~any one of the preceding claims~~, wherein said soft steroid is defined by the structural formula I:



I

wherein

R₁ is C₁-C₄ alkyl, which is unsubstituted or which bears one substituent selected from the group consisting of chloro, fluoro, C₁-C₄ alkoxy, C₁-C₄ alkylthio, C₁-C₄ alkylsulfinyl and C₁-C₄ alkylsulfonyl;

R₃ is hydrogen, α -hydroxy, β -hydroxy, α -methyl, β -methyl, $=CH_2$, or α - or β -OC(O)CHCl₂;

R₄ is hydrogen, fluoro, or chloro;

R₅ is hydrogen, fluoro, chloro or methyl;

R₆ is hydrogen, chloro or methyl;

X is -O- or -S-;

Z is carbonyl, β -hydroxymethylene or β -chloromethylene;

the dotted line in ring A indicates that the 1,2-linkage is saturated or unsaturated.

24. (original) A composition as claimed in claim 23, wherein

R₃ is H, R₄ is H or F and R₅ is H, F or CH₃; or

R₃ is α -CH₃ or CH₃, R₄ is H or F and R₅ is H, F or CH₃; or

R₃ is α -OH, β -OH, α -OCOCHCl₂ or β -OCOCHCl₂, R₄ is H or F and R₅ is H, F or CH₃.

25. (currently amended) A composition as claimed in claim 23, wherein said soft steroid comprises one or more of the following structural characteristics:

(5) (a) R₁ is unsubstituted C₁-C₄ alkyl, methyl, ethyl or chloromethyl, ~~especially when R₁ is unsubstituted alkyl, most especially when R₁ is ethyl or methyl;~~

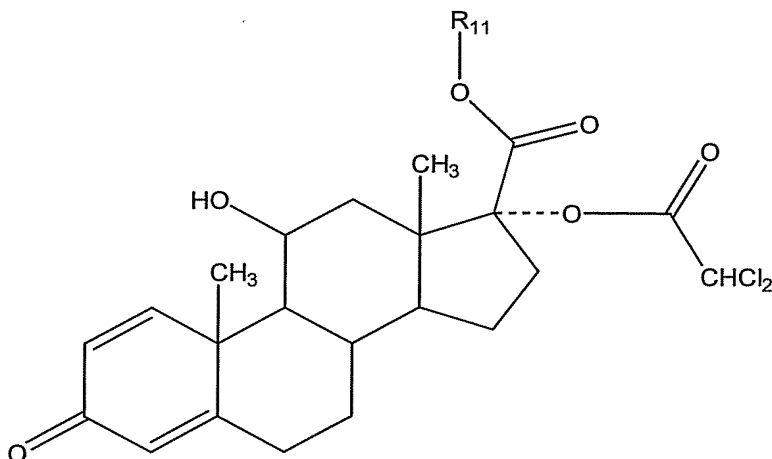
(6) (b) X is -O-;

(7) (c) Z is β -hydroxymethylene;

(d) the 1,2-linkage is unsaturated; and

(4) (e) R₆ is Cl.

26. (currently amended) A composition as claimed in claim 23, wherein said soft steroid is defined by the structural formula:

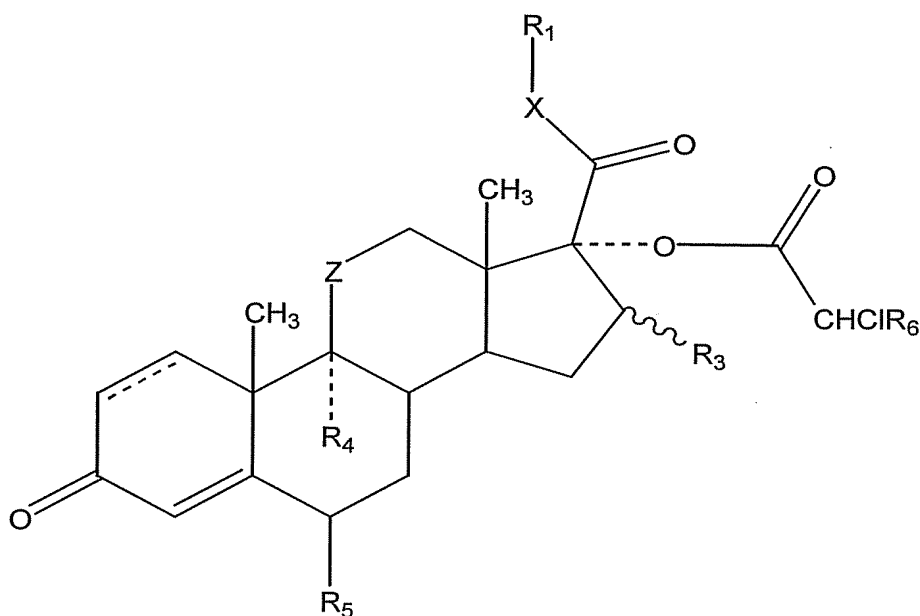


wherein R_{11} is methyl, ethyl, isopropyl or chloromethyl, ~~especially methyl, ethyl or isopropyl.~~

27. (currently amended) A composition as claimed in claim 26 ~~any one of the preceding claims~~, wherein said soft steroid is etiprednol dicloacetate.

28. (currently amended) A composition as claimed in claim 26, ~~any one of the preceding claims~~, wherein said soft steroid is loteprednol etabonate wherein R_{11} is methyl, ethyl or isopropyl.

29. (currently amended) A composition as claimed in claim 1 or 4 ~~23~~, wherein said soft steroid is defined by the structural formula II:



II

wherein

R_6 is H or CH₃ ~~CH₃~~, particularly ~~when R_6 is CH₃~~ CH₃,

R_1 is C₁-C₄ alkyl, which is unsubstituted or which bears one substituent selected from the group consisting of chloro, fluoro, C₁-C₄ alkoxy, C₁-C₄ alkylthio, C₁-C₄ alkylsulfinyl and C₁-C₄ alkylsulfonyl;

R_3 is hydrogen, α -hydroxy, β -hydroxy, α -methyl, β -methyl, =CH₂, or α - or β -OC(O)CHCl₂;

R₄ is hydrogen, fluoro, or chloro;

R₅ is hydrogen, fluoro, chloro or methyl;

X is -O- or -S-;

Z is carbonyl, β -hydroxymethylene or β -chloromethylene; and

the dotted line in ring A indicates that the 1,2-linkage is saturated or unsaturated.

30. (currently amended) A composition as claimed in claim 29 [[23]], wherein ~~the soft steroid~~ comprises the following sub-groups

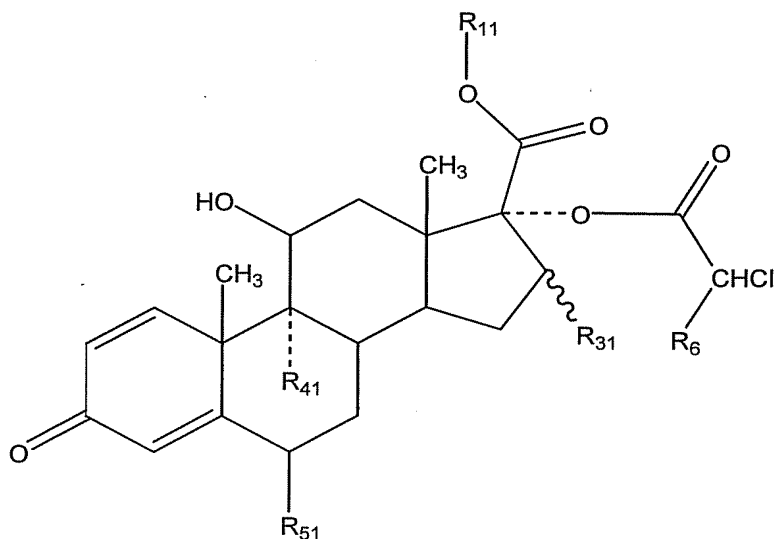
~~(4) compounds in which~~ R₃ is H, R₄ is H or F and R₅ is H, F or CH₃; or

~~(5) compounds in which~~ R₃ is α -CH₃ or β -CH₃, R₄ is H or F and R₅ is H, F or CH₃; or

~~(6) R₃ is α -OH, β -OH, α -OCOCHCl₂ or β -OCOCHCl₂, R₄ is H or F and R₅ is H, F or CH₃.~~

31-32. (canceled)

33. (currently amended) A composition as claimed in claim 29 23, wherein said soft steroid is defined by the structural formula:



wherein

R₁₁ is methyl, ethyl, isopropyl or chloromethyl[.,,];

R₃₁ is α -CH₃ or β -CH₃;

R₄₁ is H or F;

R₅₁ is H or F; and

R₆ is H or CH₃, ~~especially when R₁₁ is methyl, ethyl or isopropyl.~~

34. (currently amended) A composition as claimed in claim 1 or 4 ~~any one of the preceding claims~~, wherein said excipient comprises one or more of lactose, sucrose, glucose, mannitol, xylitol, trehalose, or other monosaccharides, disaccharides or polysaccharides, or derivatives thereof.

35. (original) A composition as claimed in claim 34, wherein said excipient is lactose monohydrate.

36. (currently amended) ~~A medicament suitable for use in a dry powder inhaler comprising particles of at least one soft steroid and at least one excipient, wherein said at least one soft steroid particles have a volume mean diameter of less than about 20 micrometers and said at least one excipient particles have a volume mean diameter in the range of about 10 to about 1000 micrometers~~ composition of claim 33, wherein R₁₁ is methyl, ethyl or isopropyl.

37-70. (canceled)

71. (original) A medicament comprising the composition of claim 1.

72. (currently amended) A medicament suitable for use in a dry powder inhaler comprising the composition as claimed in claim 1 or 4.

73. (currently amended) A method of preparing a medicament as claimed in claim 72 36, wherein said method comprises admixing particles of said soft steroid and said excipient under shear or kinetic mixing conditions.

74. (currently amended) A method of treating a respiratory tract or lung based disease or disorder in a mammal, comprising administering the ~~with a medicament of claim 72~~ administered by way of a dry powder inhaler, ~~said medicament comprising particles of at least one soft steroid and at least one excipient, wherein said at least one soft steroid particles have a volume mean diameter of less than about 20 micrometers and said at least one excipient particles have a volume mean diameter in the range of about 10 to about 1000 micrometers.~~

75. (currently amended) The method according to claim 74, wherein the ~~medicament is administered for the treatment of~~ respiratory tract or lung based disease or disorder ~~is diseases or disorders in mammals, such as asthma.~~

76-81. (canceled)